

REMARKS

The Office Action of June 2, 2006, has been considered by the Applicants. Claims 1, 8, 10, and 31-33 have been amended. New claim 34 has been added. Claims 1, 2, 4-8, and 10-34 remain pending in the Application. Reconsideration of the Application is requested.

Applicants note that new claim 34 recites a combination of current claims 7 and 8. The specification supports this new claim from page 3, line 28, to page 4, line 11.

Claims 8 and 33 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for using the trademark MACROGOL. Applicants traverse the rejection. Claims 8 and 33 have been amended to capitalize the trademark and give the generic terminology as suggested by the Examiner. The amended claims are therefore definite. Applicants request withdrawal of the § 112, ¶ 2 rejection.

Claims 1, 2, 4-7, 10-17, 24-26, and 28 were rejected under 35 U.S.C. 102(e) as anticipated by Dugger III (5,955,098). Applicants traverse the rejection.

Dugger does not teach all claim limitations. Dugger teaches the use of "chocolate powder", which Applicants interpret to be cacao powder. However, the instant claims require the use of cacao butter. Cacao powder is different from cacao butter because it does not contain crystals. The aging process results in a structural difference in the crystals in cacao butter, such that a sense of homogeneity of the shell and fill material results. See the specification on page 20, lines 10-28. Because chocolate powder does not contain crystals, curing it cannot result in a product having the same structure as aging a soft capsule at 30-40 °C with a fill comprising cacao butter. Regardless of any implied "aging" by Dugger, using chocolate powder results in a different product than from using cacao butter. Therefore, the claims are not anticipated by Dugger. Applicants request withdrawal of the 102(b) rejection over Dugger.

Claims 1, 2, 12, 17, and 27-30 were rejected under 35 U.S.C. 102(b) as anticipated by Liu (4,576,826). Applicants traverse the rejection.

Liu discloses a process for preparing flavorant capsules. Liu never teaches that the flavorant capsule comprises cacao butter, as required by the instant claims. Therefore, his product is inherently different from the soft capsules of the instant claims.

Applicants also submit that because Liu prepares flavorant capsules, they are not chewable soft capsules. As evidence, note that they are intended merely to deliver aromatic or flavor components. See col. 1, lines 8-17. Liu also continuously describes his capsule as “hard”, whereas the instant claims recite a soft capsule. See, for example, col. 2, lines 30 and 43, both reciting a “hardened shell”. Their size, from 250 μm to 3.5 mm, does not lend themselves to easy chewing. See col. 2, lines 45-50. Finally, they should dissolve in water. See col. 5, lines 1-6. This fact tends to show the capsules are not chewable.

Liu’s capsule does not contain a solid or semi-solid fill material. Liu teaches forming a hardened shell around a droplet of edible oil or frozen particles. See col. 2, lines 17-32. This shell is formed by adding emulsion to a powdered wall material. The wall material soaks up moisture from the emulsion, then dries to form a hard shell. Eventually, the capsule becomes a hardened shell surrounding a droplet of oil. See col. 5, lines 26-46. A droplet of oil is not solid or semi-solid, but liquid.

The Examiner states that Liu discloses the fill is kept at a temperature range of 0-40 °C; see col. 4, lines 11-20. Applicants note that Liu also teaches that as the temperature rises, the emulsion becomes less stable and that the temperature is preferably at ambient temperature (around 20 °C). Liu implicitly admits that the range of 30-40 °C is a temperature normally achieved only by active means, ie. heating. The Examiner also states that Liu discloses the obtained capsules are dried at room temperature over a period of time. Again, room temperature is not in the required range of 30-40 °C.

For these reasons, Liu does not anticipate the instant claims. Applicants request withdrawal of the 102(b) rejection over Liu.

Claims 1, 8, 24, and 26 were rejected under 35 U.S.C. 102(b) as anticipated by Damour (5,563,144). Applicants traverse the rejection.

Damour does not teach aging the capsule. She does not disclose a chewable soft capsule either. Indeed, the Examiner cites a section mentioning a composition comprising cacao butter for use as a suppository or a rectal capsule, not a soft chewable capsule. One might hope a rectal capsule is soft(!), but that property is not taught nor is it inherent in such a capsule. Applicants will not take a position on whether a rectal capsule is inherently chewable as claim 2 was not rejected. Therefore, Damour does not anticipate the instant claims. Applicants request withdrawal of the 102(b) rejection over Damour.

Claims 1, 8, 24, and 26 were rejected under 35 U.S.C. 102(b) as anticipated by Nitardy (2,206,113). Applicants traverse the rejection.

Permitting melted fat to cool is not equivalent to aging as described in instant claim 1, which requires the soft capsule to be maintained at a temperature of 30-40°C for 5 hours or more. Nitardy implies the melted fat is cooled to room temperature; again, this is not within the range of 30-40° C. The Examiner, in her 103 rejection on page 7, also states that Nitardy does not teach aging the fill material. Therefore, Nitardy does not anticipate the instant claims. Applicants request withdrawal of the 102(b) rejection over Nitardy.

Claims 1, 2, 4-7, 10-17, and 19-28 were rejected under 35 U.S.C. 103(a) as obvious over Scheibl or Dugger, in view of Borkan. Applicants traverse the rejection.

Not all claim limitations are taught. Dugger teaches the use of chocolate powder and Scheibl teaches the use of cacao powder. Again, these powders are different from cacao butter because they do not contain crystals. Therefore, aging them will not result in the structural difference described in the instant specification. Borkan is used to teach the shell and does not remedy this deficiency in the fill material. Therefore, the instant claims are not obvious over this combination of references. Applicants request withdrawal of the 103(a) rejection.

Claims 1, 2, 4-7, 10-17, and 19-27 were rejected under 35 U.S.C. 103(a) as obvious over Scheibl or Dugger, in view of Ebert. Applicants traverse the rejection.

Not all claim limitations are taught. Dugger teaches the use of chocolate powder and Scheibl teaches the use of cacao powder. Again, these powders are different from cacao butter because they do not contain crystals. Therefore, aging them will not result in the structural difference described in the instant specification. Ebert is used to teach the shell and does not remedy this deficiency in the fill material. Therefore, the instant claims are not obvious over this combination of references. Applicants request withdrawal of the 103(a) rejection.

Claims 28-30 were rejected under 35 U.S.C. 103(a) as obvious over Scheibl, Dugger, or Nitardy, in view of Ebert. Applicants traverse the rejection.

Claims 28-30 depend from independent claim 1. If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. MPEP § 2143.03; *In re Fine*.

This rejection depends upon room temperature being interpreted as including temperatures within the range of 30-40 °C, as the Examiner concedes neither Scheibl, Dugger, nor Nitardy teaches aging the fill material. Ebert teaches drying and the Examiner attempts to show the drying can be at room temperature by using Sacripante and Takegawa to teach that room temperature is from about 20-40 °C or 0-40 °C.

Room temperature would never be interpreted by one skilled in the art as encompassing the range of 30-40° C. For example, Webster's II New College Dictionary, ISBN 0-395-96214-5, defines room temperature as "an indoor temperature of 20 to 25 ° C".

One skilled in the art would certainly not look to Sacripante or Takegawa to learn what room temperature is. In order to rely on these references as teaching a definition of room temperature, they must be analogous prior art. To be analogous, they must either be in the field of Applicants' endeavor or be reasonably pertinent to the particular problem with which the invention is concerned. MPEP § 2141.01(a)(I). Sacripante and Takegawa are not analogous. As partial evidence, they are in different classes from the instant application because they deal with different subject matter. Sacripante deals with ink compositions and is listed in class 106. Takegawa deals with fabricating electrodes for discharge lamps and is international class H01J, corresponding roughly to US class 315. This application, on the other hand, is being examined in class 424. Neither reference would logically have commended itself to an artisan's attention in considering what temperature to dry an ingestible capsule either. Therefore, they cannot be considered analogous and should not be relied on as teaching that room temperature encompasses the range of 30-40 °C. It may be obvious in light of Scheibl, Dugger, Nitardy, and Ebert to dry the capsule, but mere use of the term "drying" is not equivalent to maintaining the temperature between 30-40 °C for five hours or more, as required by claim 1.

On page 10 of the Office Action, the Examiner stated that aging the fill material above room temperature was not recited in the rejected claims. This statement is incorrect; the examined claims recited aging at a temperature of 30-40 °C. As discussed above, this is above room temperature.

For these reasons, Applicants request withdrawal of the 103(a) rejection.

Claims 8 and 31-33 were rejected under 35 U.S.C. 103(a) as obvious over Scheibl or Dugger, in view of Perry (EP 0904064) and Miyake (4,219,439). Applicants traverse the rejection.

Claims 8 and 31-33 depend from independent claim 1. If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. MPEP § 2143.03; *In re Fine*. Neither Dugger nor Scheibl render claim 1 obvious because, among other things, they do not teach aging the cacao butter to achieve the structural differences therefrom. Neither Perry nor Miyake remedy this deficiency and this combination of references therefore cannot render claims 8 and 31-33 obvious. Applicants request withdrawal of the 103(a) rejection.

Claim 18 was rejected under 35 U.S.C. 103(a) as obvious over Scheibl or Dugger, in view of Mehta. Applicants traverse the rejection.

Claim 18 depends from independent claim 1. If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. MPEP § 2143.03; *In re Fine*. Neither Dugger nor Scheibl render claim 1 obvious because, among other things, they do not teach aging the cacao butter to achieve the structural differences therefrom. Mehta does not remedy this deficiency and this combination of references therefore cannot render claim 18 obvious. Applicants request withdrawal of the 103(a) rejection.

On page 11 of the Office Action, the Examiner notes that the structural difference upon which Applicants rely is not recited in the rejected claims. In response to this comment, Applicants state that claim 1 should be interpreted as a product-by-process claim. The structure implied by the process steps should be considered when assessing the patentability of the instant claims over the prior art. Here, the aging step imparts distinctive structural characteristics. MPEP § 2113. The Examiner has implicitly recognized the structural differences by attempting to find teachings in the prior art that match the aging step.

The Examiner had some questions in a telephone interview conducted on March 28, 2006. Applicants wish to respond to those questions.

The Examiner wished to know whether the aging step could comprise just the fill material alone or if the shell material was needed. The aging process can be carried out on the fill material alone, as demonstrated in Production Examples 29 and 30 on page 36 of the specification. The aging process can also be carried on a filled shell, as demonstrated in Example 12 on page 38 of the specification. During practical application,

the aging would most likely be carried out on the shell and fill material together after encapsulation, as described in Figure 1 and as recited in the newly amended claims.

The Examiner wished to know whether the shell is molded around the fill material or whether shells are first formed and the fill material is then injected or added into the shell. Any process known in the art to fill a soft capsule can be used, and the specific method is not connected to the claimed invention. The reference cited on page 19 of the specification describes soft capsules which are filled with a liquid.

CONCLUSION


For the reasons given above, it is respectfully submitted all pending claims (1, 2, 4-8, and 10-34) are now in condition for allowance. Withdrawal of the rejections and issuance of a Notice of Allowance is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, she is hereby authorized to call Richard M. Klein, at telephone number 216-861-5582, Cleveland, OH.

Respectfully submitted,

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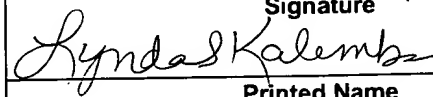
September 5, 2006
Date


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